IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OMEROS CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. _____
	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Omeros Corporation, by its undersigned attorneys, brings this action against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Defendants" or "Lupin"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, et seq., arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 210183 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market a generic version of the pharmaceutical product OMIDRIA® (phenylephrine and ketorolac injection, 1%/0.3%) prior to the expiration of United States Patent No. 8,173,707; United States Patent No. 8,586,633; United States Patent No. 9,066,856; United States Patent No. 9,278,101; United States Patent No. 9,399,040; and United States Patent No. 9,486,406. Plaintiff seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff Omeros Corporation is a corporation organized and existing under the laws of the State of Washington, and having a place of business at 201 Elliott Avenue West,

Seattle, Washington 98119. Omeros is a biopharmaceutical company committed to discovering, developing and commercializing both small-molecule therapeutics and protein therapeutics.

3. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, and having a principal place of business at B/4, Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra, India.

4. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 111 S. Calvert Street, Floor 21, Baltimore, Maryland 21202-6174. On information and belief, Lupin Pharmaceuticals, Inc. has facilities in Somerset, New Jersey at which research, development and manufacturing activities take place.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Defendant Lupin Ltd.

6. On information and belief, Defendants collaborate with respect to the development, regulatory approval, marketing, sale and/or distribution of pharmaceutical products.

7. On information and belief, Defendants collaborated in the preparation and submission of ANDA No. 210183 (the "Lupin ANDA") and continue to collaborate in seeking FDA approval of that application.

8. On information and belief, Defendants intend to collaborate in the commercial manufacture, marketing, offer for sale, and sale of the product described in the Lupin ANDA (the "ANDA Product") throughout the United States, including in the State of New Jersey, in the event the FDA approves the Lupin ANDA.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of United States Patent No. 8,173,707; United States Patent No. 8,586,633; United States Patent No. 9,066,856; United States Patent No. 9,278,101; United States Patent No. 9,399,040; and United States Patent No. 9,486,406. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

10. On information and belief, this Court has personal jurisdiction over Defendant Lupin Ltd. because, inter alia, its fully owned subsidiary Lupin Pharmaceuticals, Inc., has a place of business in New Jersey.

11. This Court also has personal jurisdiction over Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc., because each Defendant has continuous and systematic contacts with New Jersey. On information and belief, Lupin Pharmaceuticals, Inc. has a place of business in New Jersey. Further, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures OMIDRIA for sale and use throughout the United States, including this judicial district.

12. In addition, this Court has personal jurisdiction over Lupin because Lupin Ltd. and Lupin Pharmaceuticals, Inc., regularly engage in patent litigation concerning FDA-approved drug products in this District and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Janssen Prods. L.P. v. Lupin Ltd. et al.*, 109 F. Supp. 3d 650 (D.N.J. 2014); *Elan Pharma Int'l Ltd. v. Lupin Ltd & Lupin Pharms., Inc.*, No. 09-1008, 2010 WL 1372316 (D.N.J. 2016).

13. Venue is proper in this district for Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. § 1400 because, on information and belief, Lupin Pharmaceuticals, Inc. has a regular and established place of business in New Jersey. Venue is proper in this district for Lupin Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400, including because, on information and belief, Lupin Ltd.'s fully owned subsidiary Lupin Pharmaceuticals, Inc., has a regular and established place of business in New Jersey.

OMEROS'S APPROVED OMIDRIA DRUG PRODUCT AND PATENTS

14. Omeros makes and sells OMIDRIA, a combination product used during cataract surgery or intraocular lens replacement to maintain pupil size by preventing miosis and to reduce postoperative pain. OMIDRIA contains two active ingredients: phenylephrine hydrochloride and ketorolac tromethamine.

15. OMIDRIA is the first FDA-approved product for intraocular use during cataract surgery or intraocular lens replacement that both prevents intraoperative miosis (pupil constriction) and reduces postoperative pain.

16. Omeros is the holder of New Drug Application ("NDA") No. 205388 for OMIDRIA. The FDA approved NDA No. 205388 for OMIDRIA in May 2014, and granted OMIDRIA three years of regulatory exclusivity pursuant to 21 C.F.R. 314.108.

17. Omeros owns United States Patent No. 8,173,707 (the "'707 Patent"); United States Patent No. 8,586,633 (the "'633 Patent"); United States Patent No. 9,066,856 (the "'856 Patent"); United States Patent No. 9,278,101 (the "'101 Patent"); United States Patent No. 9,399,040 (the "'040 Patent"); and United States Patent No. 9,486,406 (the "'406 Patent").

18. The '707 Patent, the '633 Patent, the '856 Patent, the '101 Patent, the '040 Patent, and the '406 Patent are listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for OMIDRIA.

19. The '707 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on May 8, 2012. A true and correct copy of the '707 Patent is attached as Exhibit A.

20. The '633 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the USPTO on November 19, 2013. A true and correct copy of the '633 Patent is attached as Exhibit B.

21. The '856 Patent, entitled "Stable Preservative-Free Mydriatic and Anti-inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on June 30, 2015. A true and correct copy of the '856 Patent is attached as Exhibit C.

22. The '101 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duly and lawfully issued by the USPTO on March 8, 2016. A true and correct copy of the '101 Patent is attached as Exhibit D.

23. The '040 Patent, entitled "Ophthalmologic Irrigation Solutions and Method," was duty and lawfully issued by the USPTO on July 26, 2016. A true and correct copy of the '040 Patent is attached as Exhibit E.

24. The '406 Patent, entitled "Stable Preservative-free Mydriatic and Anti-inflammatory Solutions for Injection," was duly and lawfully issued by the USPTO on November 8, 2016. A true and correct copy of the '406 Patent is attached as Exhibit F.

DEFENDANTS' ANDA

25. On information and belief, Defendants have submitted or caused to be submitted ANDA No. 210183 to the FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of ketorolac tromethamine, phenylephrine hydrochloride solution, as a purported generic version of OMIDRIA, prior to the expiration of the '707, '633, '856, '101, '040, and '406 Patents.

26. On information and belief, on or about May 12, 2017, Defendant Lupin Ltd. mailed Plaintiff a letter regarding "OMIDRIA® (phenylephrine and ketorolac injection), 1 %/0.3%[,] ANDA No. 210183[,] U.S. Patent Nos. 8,173,707, 8,586,633, 9,066,856, 9,278,101, 9,399,040, and 9,486,406" (the "Notice Letter"). The Notice Letter represented that Defendant Lupin Ltd. has submitted to the FDA ANDA No. 210183 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the product described in the Lupin ANDA before the expiration of the patents listed in the Orange Book for OMIDRIA. Hence, Defendants' purpose in submitting the Lupin ANDA is to manufacture and market the ANDA Product before the expiration of the '707, '633, '856, '101, '040, and '406 Patents.

27. Lupin's Notice Letter stated that the Paragraph IV certification in the Lupin ANDA alleges that no valid claim of the '707, '633, '856, '101, '040, and '406 Patents will be infringed by the manufacture, importation, use, or sale of the ANDA Product.

28. Lupin's Notice Letter contained "Lupin's Detailed Factual and Legal Bases in Support of Its Paragraph IV Certification for Ketorolac Tromethamine; Phenylephrine Hydrochloride Solution (0.3% eq./1% eq.)" ("Detailed Statement").

29. Lupin's Detailed Statement, however, did not identify any theory of non-infringement for the '707 Patent, the '633 Patent, claims 1-3 and 8-13 of the '101 Patent, the '040 Patent, the '856 Patent, or the '406 Patent.

30. After receiving Lupin's Notice Letter and accompanying Offer of Confidential Access, Plaintiff wrote to Lupin in an effort to negotiate reasonable terms of access to the Lupin ANDA. The parties agreed on terms for the OCA on June 9, 2017. Plaintiff received Lupin's ANDA on the same day.

31. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Lupin ANDA, have provided material support to the preparation and submission of the Lupin ANDA, and intend to support the further prosecution of the Lupin ANDA.

32. On information and belief, if the FDA approves the Lupin ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Product within the United States, including within New Jersey, or will import the ANDA Product into the United States, including New Jersey.

33. On information and belief, if the FDA approves the Lupin ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product.

34. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiff's receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE '707 PATENT

35. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

36. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

37. Defendants have infringed the '707 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '707 Patent.

38. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement

of the '707 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent.

39. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '707 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '707 Patent and knowledge that they are encouraging infringement.

40. Defendants had actual and constructive notice of the '707 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '707 Patent would constitute an act of infringement of the '707 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '707 Patent.

41. Lupin's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '707 Patent.

42. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '707 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '707 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

43. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '707 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '707 PATENT

44. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–43 as if fully set forth herein.

45. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. On information and belief, if the Lupin ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates.

47. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA

and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

48. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '707 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '707 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

49. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '707 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

50. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

51. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '633 PATENT

52. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

53. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

54. Defendants have infringed the '633 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '633 Patent.

55. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of the '633 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent.

56. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '633 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '633 Patent and knowledge that they are encouraging infringement.

57. Defendants had actual and constructive notice of the '633 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '633 Patent would constitute an act of infringement of the

'633 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '633 Patent.

58. Lupin's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '633 Patent.

59. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '633 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '633 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

60. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '633 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '633 PATENT

61. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 and 52–60 as if fully set forth herein.

62. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. On information and belief, if the ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates.

64. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

65. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '633 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '633 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

66. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '633 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

67. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

68. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '856 PATENT

69. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

70. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

71. Defendants have infringed the '856 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '856 Patent.

72. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, and/or would actively induce and contribute to infringement of the '856 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '856 Patent.

73. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '856 Patent. In addition, on information and belief, Defendants will encourage acts of direct

infringement with knowledge of the '856 Patent and knowledge that they are encouraging infringement.

74. Defendants had actual and constructive notice of the '856 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '856 Patent would constitute an act of infringement of the '856 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '856 Patent.

75. Lupin's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '856 Patent.

76. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '856 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '856 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

77. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '856 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '856 PATENT

78. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–33 and 69–77 as if fully set forth herein.

79. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

80. On information and belief, if the Lupin ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates. Defendants will therefore infringe one or more claims of the '856 Patent under 35 U.S.C. § 271(a).

81. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

82. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '856 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '856 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

83. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '856 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

84. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

85. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '101 PATENT

86. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

87. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

88. Defendants have infringed the '101 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA and seeking FDA approval of the Lupin ANDA prior to the expiration of the '101 Patent.

89. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of one or more claims of the '101 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent.

90. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals, and other clinics, health care professionals, and end users of the ANDA Product. On information and

belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '101 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '101 Patent and knowledge that they are encouraging infringement.

91. Defendants had actual and constructive notice of the '101 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '101 Patent would constitute an act of infringement of the '101 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '101 Patent.

92. Defendants' Detailed Statement in its Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of claims 1-3 and 8-13 of the '101 Patent.

93. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '101 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '101 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

94. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of claims of the '101

Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '101 PATENT

95. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 and 86–94 as if fully set forth herein.

96. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

97. On information and belief, if the Lupin ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates.

98. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

99. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '101 Patent expires will contribute to the infringement of and/or induce the infringement of one or more claims of the '101 Patent under one or more of 35 U.S.C. §§ 271(b), (c), (f) and (g).

100. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the

infringement of claims of the '101 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

101. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

102. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IX
INFRINGEMENT OF THE '040 PATENT

103. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

104. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

105. Defendants have infringed the '040 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '040 Patent.

106. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would actively induce and/or contribute to infringement of the '040 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of and/or induce the infringement of one or more claims of the '040 Patent.

107. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '040 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '040 Patent and knowledge that they are encouraging infringement.

108. Defendants had actual and constructive notice of the '040 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '040 Patent would constitute an act of infringement of the '040 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not contribute to the infringement of and/or induce the infringement of the '040 Patent.

109. Lupin's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '040 Patent.

110. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '040 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying

invalidity, unenforceability and/or non-infringement with respect to the '040 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

111. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '040 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '040 PATENT

112. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 and 103–111 as if fully set forth herein.

113. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

114. On information and belief, if the Lupin ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates. Defendants will therefore infringe one or more claims of the '040 Patent under 35 U.S.C. § 271(a).

115. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '040 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

116. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any

such conduct before the '040 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '040 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

117. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '040 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

118. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

119. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT XI
INFRINGEMENT OF THE '406 PATENT

120. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 as if fully set forth herein.

121. On information and belief, Defendants have submitted or caused the submission of the Lupin ANDA to the FDA, and continue to seek FDA approval of the Lupin ANDA.

122. Defendants have infringed the '406 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Lupin ANDA with a Paragraph IV certification and seeking FDA approval of the Lupin ANDA prior to the expiration of the '406 Patent.

123. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product would directly infringe, and/or would actively induce and contribute to infringement of the '406 Patent. Accordingly, unless enjoined by this Court,

upon FDA approval of ANDA No. 210183, Defendants will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '406 Patent.

124. On information and belief, upon FDA approval of ANDA No. 210183, Defendants will market and distribute the ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the ANDA Product. On information and belief, Defendants will also knowingly and intentionally accompany the ANDA Product with a product label and product insert that will include instructions for using and administering the ANDA Product. Accordingly, Defendants will induce health care professionals, resellers, pharmacies, and end users of the ANDA Product to directly infringe one or more claims of the '406 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '406 Patent and knowledge that they are encouraging infringement.

125. Defendants had actual and constructive notice of the '406 Patent prior to filing the Lupin ANDA, and were aware that the filing of the Lupin ANDA with the request for FDA approval prior to the expiration of the '406 Patent would constitute an act of infringement of the '406 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '406 Patent.

126. Lupin's Detailed Statement in the Notice Letter lacks any contention that the ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the '406 Patent.

127. In addition, Defendants filed the Lupin ANDA without adequate justification for asserting the '406 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendants' conduct in certifying invalidity, unenforceability and/or non-infringement with respect to the '406 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

128. Plaintiff will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '406 Patent. Plaintiff does not have an adequate remedy at law, and considering the balance of hardships between Plaintiff and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '406 PATENT

129. Plaintiff restates, realleges, and incorporates by reference paragraphs 1–34 and 120–128 as if fully set forth herein.

130. Plaintiff's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

131. On information and belief, if the Lupin ANDA is approved, the ANDA Product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of New Jersey, by or through Defendants and their affiliates. Defendants will therefore infringe one or more claims of the '406 Patent under 35 U.S.C. § 271(a).

132. On information and belief, Defendants know that health care professionals or patients will use the ANDA Product in accordance with the labeling sought by the Lupin ANDA and Defendants will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the '406 Patent under one or more of 35 U.S.C. §§ 271 (b), (c), (f) and (g).

133. On information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of the ANDA Product complained of herein will begin immediately after the FDA approves the Lupin ANDA. Any such conduct before the '406 Patent expires will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '406 Patent under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g).

134. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiff and Defendants concerning liability for the infringement of the '406 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

135. Plaintiff will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

136. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '707 Patent was an act of infringement of one or more claims of the '707 Patent;

(B) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial

manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '633 Patent was an act of infringement of one or more claims of the '633 Patent;

(C) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '856 Patent was an act of infringement of one or more claims of the '856 Patent;

(D) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '101 Patent was an act of infringement of one or more claims of the '101 Patent;

(E) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '040 Patent was an act of infringement of one or more claims of the '040 Patent;

(F) A declaratory judgment that under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of ANDA No. 210183 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product before the expiration of the '406 Patent was an act of infringement of one or more claims of the '406 Patent;

(G) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '707 Patent;

(H) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '633 Patent;

(I) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '856 Patent;

(J) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '101 Patent;

(K) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '040 Patent;

(L) A declaratory judgment that under one or more of 35 U.S.C. §§ 271(a), (b), (c), (f) and (g), Defendants' commercial manufacture, use, offer for sale, or sale in, or importation

into, the United States of the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of one or more claims of the '406 Patent;

(M) The entry of a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, using, offering for sale, or selling the ANDA Product within the United States, or importing the ANDA Product into the United States, until the expiration of the '707, '633, '856, '101, '040, and '406 Patents;

(N) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 210183 shall be no earlier than the last expiration date of any of the '707, '633, '856, '101,'040, and '406 Patents, or any later expiration of exclusivity for any of the '707, '633, '856, '101, '040, and '406 Patents, including any extensions or regulatory exclusivities;

(O) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '707 Patent, or induces or contributes to such conduct, prior to the expiration of the '707 Patent;

(P) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '633 Patent, or induces or contributes to such conduct, prior to the expiration of the '633 Patent;

(Q) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

the ANDA Product, or any product that infringes the '856 Patent, or induces or contributes to such conduct, prior to the expiration of the '856 Patent;

(R) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '101 Patent, or induces or contributes to such conduct, prior to the expiration of the '101 Patent;

(S) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '040 Patent, or induces or contributes to such conduct, prior to the expiration of the '040 Patent;

(T) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '406 Patent, or induces or contributes to such conduct, prior to the expiration of the '406 Patent;

(U) The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiff its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(V) An award to Plaintiff of its costs and expenses in this action; and

(W) Such other and further relief as the Court deems just and proper.

Respectfully submitted,

/s/ Nicholas M. Insua
Nicholas M. Insua
Cynthia S. Betz
McCARTER & ENGLISH, LLP
100 Mulberry Street
4 Gateway Center
Newark, NJ 07102
(973) 622-4444

Attorneys for Plaintiff

OF COUNSEL:
George F. Pappas
Jeffrey Lerner
Gary M. Rubman
Courtney R. Forrest
Meghan Monaghan
COVINGTON &BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

June 22, 2017

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the matter in controversy is the subject of the action *Omeros Corporation v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, filed in the United States District Court for the District of Delaware on June 22, 2017. No case number is yet assigned.

Dated: June 22, 2017

Respectfully submitted,

/s/ Nicholas M. Insua

Nicholas M. Insua
Cynthia S. Betz
McCARTER & ENGLISH, LLP
100 Mulberry Street
4 Gateway Center
Newark, NJ 07102
(973) 622-4444

OF COUNSEL:
George F. Pappas
Jeffrey Lerner
Gary M. Rubman
Courtney R. Forrest
Meghan Monaghan
COVINGTON & BURLING, LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000